UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,048	06/08/2005	Michael West	181-183	6789

23117 7590 12/06/2007
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
OLSON, ERIC	
ART UNIT	**PAPER NUMBER**
1623	
MAIL DATE	**DELIVERY MODE**
12/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,048	WEST ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 25-27* is/are rejected.

7)☒ Claim(s) *3 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted October 18, 2007 wherein claims 1 and 4-27 are amended. This application is a national stage application of PCT/AU03/01008, filed August 8, 2003, which claims priority to foreign application AU20020950657, filed August 8, 2002.

Claims 1-27 are pending in this application.

Newly amended claims 6-24 as amended are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These claims are directed to a synthetic method for making a compound of claim 1. This method lacks a shared special technical feature with the originally presented invention. In particular, while both groups involve the structure of formula I, recited in instant claim 1, this generic structure is an obvious variant of the prior art, as described below. Any novel or non-obvious invention would be directed to specific modifications or embodiments of the claimed structure, rather than to the generic structure as a whole. Therefore there is no shared special technical feature over the prior art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-5 and 25-27 as amended are examined on the merits herein.

Applicant's references, submitted October 18, 2007, with respect to the rejection of instant claims 1-27 under 35 USC 101 and 112, first paragraph, for lacking an asserted, credible utility, have been fully considered and found to be persuasive to remove the rejection as the references indicate that the compounds can reasonably be screened for certain specific biological activities.. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claims 6-21 under 35 USC 112, second paragraph, for reciting the indefinite phrase, "comprise as a precursor," has been fully considered and found to be persuasive to remove the rejection as these claims no longer contain said limitation. Therefore the rejection is withdrawn. Note, however, that these claims as amended have been withdrawn from consideration as belonging to a non-elected invention.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claims 1-27 under 35 USC 112, second paragraph, for reciting indefinite structural limitations for the claimed invention, has been fully considered and found to be persuasive to remove the rejection as these claims as amended no longer reference a "derivative of a monosaccharide, and additionally give a clear limiting definition of a substituent. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claims 1, 2, and 4 under 35 USC 102(b) for being anticipated by

Christ et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the compound be a monosaccharide. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claims 1, 3, and 26 under 35 USC 102(e) for being anticipated by Lin et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the compound be a monosaccharide. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claims 1, 3, and 26 under 35 USC 102(e) for being anticipated by Lin et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the compound be a monosaccharide. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claim 27 under 35 USC 103(a) for being obvious over Lin et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the compound be a monosaccharide. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claims 1, 2, 4, and 22-26 under 35 USC 103(a) for being obvious over Hanessian et al. in view of Carey et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to define the "optionally substituted C6 to C15 aralkyl" or claim 1 as having one of a set of limited, clearly defined substituents that do not include a solid support. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, with respect to the rejection of instant claims 1, 2, and 4 under 35 USC 103(a) for being obvious over Fukase et al. in view of Carey et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to define the "optionally substituted C6 to C15 aralkyl" or claim 1 as having one of a set of limited, clearly defined substituents that does not include the complex substituent of compound 3 of Fukase et al. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 18, 2007, necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al. (US patent 7138531, cited in PTO-892) Sas et al. Discloses a method of making a monosaccharide macrolide compound having antibacterial, antiviral, antitumor, and antiprotazoal activity. (column 6 lines 8-19, column 7 lines 44-48, and columns 37-42) A generic structure for this class of compounds is disclosed in which the 2-O and 3-O positions are either unsubstituted or substituted with methyl, ethyl, allyl, or benzyl. (column 7, lines 1-43) A particular synthetic scheme for making these compounds is disclosed. One intermediate in this synthesis is a monosaccharide falling within the limits of instant claim 1 except for the presence of two identical methyl ethers at positions R2 and R3. (Figure 10, sheet 7 of 14 in the drawings, compound 7.14) Sas et al. does not disclose a compound in which R2 and R3 are not both methyl. Sas et al. also does not disclose a compound in which R1 falls within the Markush group recited in instant claim 25, for example methylphenylthioether.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the synthetic scheme of Sas et al. in order to produce a compound having two dissimilar ethers at positions R2 and R3, for example methyl and ethyl, or one in which one of R2 and R3 is hydrogen, and additionally having a p-methylphenyl thioether group at R1 as described in instant claim 25, and to produce said compound by a synthetic scheme that therefore involves a compound falling within the limits of the

instant claims. One of ordinary skill in the art would have been reasonably motivated to make these compounds because they fall within the general formula described by Sas et al. One of ordinary skill in the art would reasonably have expected success because all of these groups are stable to the synthetic transformations performed in the disclosed synthetic scheme. Furthermore, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. See *In re* Lincoln, 126 USPQ 477, 53 USPQ 40 (CCPA 1942); *In re* Druey, 319 F.2d 237, 138 USPQ 39 (CCPA 1963); *In re* Lohr, 317 F.2d 388, 137 USPQ 548 (CCPA); *In re* Hoehsema, 399 F.2d 269, 158 USPQ 598 (CCPA 1968); *In re* Wood, USPQ 148 (CCPA 1977); *Ex parte* Fauque, 121 USPQ 425 (POBA 1954); *Ex parte* Henkel, 130 USPQ 474, (POBA 1960) Therefore one of ordinary skill in the art would have recognized that methyl and ethyl ethers, or phenyl and p-methylphenyl thioethers, would be expected to have the same or similar biological activity in the methods disclosed by Sas et al.

Thus the invention taken as a whole is *prima facie* obvious. Because Applicant's amendments necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 1, 2, 4, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US patent 7232900, cited in PTO-892) in view of Carey et a., (Reference of record in previous action) in view of Carey et al. part B. (Reference included with PTO-892) Johnson et al. discloses a method of making aminoalkyl glycosaminide phosphates and disaccharides. (column 2, lines 50-55) One

step in the process of making these molecules involves reacting a glycosyl chloride with another monosaccharide having a structure close to formula I disclosed in instant claim 1. (column 11, lines 16-33) The differences between the disclosed compound and the claimed subject matter are the use of a silyl protecting group at position R2 instead of an ether as disclosed in the instant claims, and the use of a trichloroethylcarbamoyl protecting group for the 1-N position instead of the non-carbamoyl substituents recited in instant claims 1 and 27.

Carey et al. discloses that various other protecting groups besides trichloroethylcarbamoyl may be used to protect amines during synthesis. (pp. 831-835) For example, the haloacetamide, benzamide, pentenoyl, and phenylsulfonamide protecting groups can all be used to protect amines.

Carey et al. part B. discloses various hydroxyl protecting groups. (pp. 823-830) For example, tetrahydropyranyl, methoxymethyl, methylthiomethyl, trichloroethoxymethyl, benzyl, methoxybenzyl, methoxyphenyl, and allyl ethers are useful as hydroxyl protecting groups, and additionally fall within the definition of the group R in instant claim 1. Benzyl additionally falls within the limits of instant claim 26 as Y3.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the protecting groups disclosed by Carey et al. and Carey et al. part B in place of the TBS and Troc protecting groups used in the aforementioned intermediate of Johnson et al., thus arriving at a compound that falls within the limitations of the instant claims. One of ordinary skill in the art would have been motivated to practice the

invention in this manner because Carey et al. discloses that these protecting groups are useful for protecting amines and hydroxyls during synthesis. One of ordinary skill in the art would have reasonably expected success because the recited protecting groups are well known in the art and utilizing them in a synthesis is well within the ordinary and routine level of skill in the art, and these protecting groups would reasonably be expected to function equivalently to those used by Johnson et al.

Furthermore, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. See *In re* Lincoln, 126 USPQ 477, 53 USPQ 40 (CCPA 1942); *In re* Druey, 319 F.2d 237, 138 USPQ 39 (CCPA 1963); *In re* Lohr, 317 F.2d 388, 137 USPQ 548 (CCPA); *In re* Hoehsema, 399 F.2d 269, 158 USPQ 598 (CCPA 1968); *In re* Wood, USPQ 148 (CCPA 1977); *Ex parte* Fauque, 121 USPQ 425 (POBA 1954); *Ex parte* Henkel, 130 USPQ 474, (POBA 1960) Therefore one of ordinary skill in the art would have recognized that the p-methylphenylsulfonamide protecting group recited in instant claim 27 would be expected to have the same or similar utility in the synthesis disclosed by Johnson et al. to the phenylsulfonamide protecting group recited by Carey et al.

Thus the invention taken as a whole is *prima facie* obvious. Because Applicant's amendments necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 1, 2, 4, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukase at al. (Reference of record in previous action) in view of Carey et al. (Reference of record in previous action) in view of Carey et al. part B.

(Reference included with PTO-892) Fukase et al. discloses certain synthetic intermediates such as compound 17 on p. 1695, scheme 3, that fall within the limitations of instant claim 1. In particular, they fall within formula I of claim 1 when R1 = O-allyl, R2 = NH-Fmoc, R3 = O-(p.methoxyphenylmethyl), R4 = p-azidobenzyl, and R5 = OH. However, Fukase et al. does not disclose a compound having a N(Y)Z group that is not recited in the exclusionary proviso of instant claim 1, found on p. 5 of the claims. Fukase et al. also differs from the claimed invention in that the methoxyphenylmethyl substituent does not bear one of the approved substituents recited by the amendment to instant claim 1.

Carey et al. discloses that various other protecting groups besides Cbz may be used to protect amines during synthesis. (pp. 831-835) For example, the allyl carbamate, nitrobenzyl carbamate, trifluoroethyl carbamate, pentenoyl, and phenylsulfonamide protecting groups can all be used to protect amines.

Carey et al. part B. discloses various hydroxyl protecting groups. (pp. 823-830) For example, tetrahydropyranyl, methoxymethyl, methylthiomethyl, trichloroethoxymethyl, benzyl, methoxybenzyl, methoxyphenyl, and allyl ethers are useful as hydroxyl protecting groups, and additionally fall within the definition of the group R in instant claim 1. Benzyl additionally falls within the limits of instant claim 26 as Y3.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compound of Fukase et al. with any of the other protecting groups mentioned by Carey et al. in place of Fmoc. One of ordinary skill in the art would have

been motivated to practice the invention in this manner because Carey et al. discloses that these protecting groups are useful for protecting amines during synthesis. One of ordinary skill in the art would have reasonably expected success because the recited protecting groups are well known in the art and utilizing them in a synthesis is well within the ordinary and routine level of skill in the art.

It would also have been obvious to one of ordinary skill in the art at the time of the invention to use the hydroxyl-protecting groups of Carey et al. part B in place of the allyl and oMPM protecting groups in compound 17 of Fukase et al. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Carey et al. discloses that these protecting groups are useful for protecting hydroxyls during synthesis. One of ordinary skill in the art would have reasonably expected success because the recited protecting groups are well known in the art and utilizing them in a synthesis is well within the ordinary and routine level of skill in the art.

Furthermore, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. See *In re* Lincoln, 126 USPQ 477, 53 USPQ 40 (CCPA 1942); *In re* Druey, 319 F.2d 237, 138 USPQ 39 (CCPA 1963); *In re* Lohr, 317 F.2d 388, 137 USPQ 548 (CCPA); *In re* Hoehsema, 399 F.2d 269, 158 USPQ 598 (CCPA 1968); *In re* Wood, USPQ 148 (CCPA 1977); *Ex parte* Fauque, 121 USPQ 425 (POBA 1954); *Ex parte* Henkel, 130 USPQ 474, (POBA 1960) Therefore one of ordinary skill in the art would have recognized that the p-methylphenylsulfonamide protecting group recited in instant

claim 27 would be expected to have the same or similar utility in the synthesis disclosed by Johnson et al. to the phenylsulfonamide protecting group recited by Carey et al.

Thus the invention taken as a whole is *prima facie* obvious. Because Applicant's amendments necessitated this new ground of rejection, the rejection is made **FINAL**.

The following grounds of rejection of record in the previous office action are maintained:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/491070. (US patent publication 20030232766, Reference of record in

previous office action, herein referred to as '070) Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of '070 substantially overlaps the claimed invention. In particular, when R4 and R5 of claim 1 of '070 are OH, R3 is hydrogen, R1 = carboxymethyl, and R = O-Y, the resulting compound falls within the limits of the claimed invention. Therefore the claimed invention is anticipated by claim 1 of '070.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument: Applicant's arguments, submitted October 18, 2007, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that R4 and R5 in the instant claims cannot form a ring. Although this is true, when R4 and R5 of '070 are hydrogen and R3 is a carboxy-, sulfonate-, or sulfonamido- methylene group, the compounds still fall within the limits of the instant claims. Therefore the rejection is deemed proper and made **FINAL**.

Conclusion

Claims 1, 2, 4, and 25-57 are rejected. Claims 3 and 5 are objected to for depending from a rejected base claim but would be allowable if rewritten in independent form including all limitations of the rejected base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson
Patent Examiner
AU 1623
11/29/07

Anna Jiang
12/4/07
Supervisory Patent Examiner
AU 1623